DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

7004 '99 SEP 30 P1:48

MAR 30 1999

Mr. Keith Pope
Developer
The Tech Museum of Innovation
145 West San Carlos Street
San Jose, California 95020

Dear Mr. Pope:

Your request of March 12, 1999, for a variance from the requirements of 21 CFR 1040.11(c) has been reviewed. A review of our records indicates that we have not yet received a report on your laser light shows as required by 21 CFR 1002.10 and 1002.12. Your variance request will not be processed further pending receipt of the report. Our experience over the past decade confirms the necessity for receiving and reviewing these reports prior to the granting of variances. We believe that to reasonably assure the public safety, we need the assurance from the reports that the applicant specifically understands how to implement the safety requirements that will be imposed by the variance and will have an adequate system of procedures and records that will document compliance with the safety requirements.

A manufacturer of a laser product is any person who manufactures, imports or assembles a product which incorporates a laser or is intended to incorporate a laser whether or not he manufactures the laser. Manufacturers or importers of lasers and laser products are required by the provisions of PL 900-602, Chapter V of the Federal Food, Drug and Cosmetic Act (the Act), Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) to furnish reports and maintain records on such products and to comply with the performance standard(s) as applicable. All laser products manufactured on or after August 2, 1976, except as noted in the standard, must be certified by their manufacturers as in compliance with the Federal performance standard as described in Sections 1040.10 and 1040.11 of the Regulations for the Enforcement of the Act. Failure to certify products as required by Section 1010 or to provide the reports or maintain the required records are violations of Section 538 of the Act and may result in the imposition of the penalties specified in Section 539.

The reporting and recordkeeping requirements are set down in Section 1002. In brief, the requirements for manufacturers and producers of laser light show products and productions are as follows:

1. a report on the laser projection system if it is not purchased as a certified laser projection system, including any auxiliary components, in accordance with the general reporting guide, "Guide for Preparing Initial and Model Change Reports on Lasers and Products Containing Lasers,";

2. a detailed report on the laser light show or display, including quality control or testing procedures, installation diagrams, and the types of effects incorporated into the laser light show, in accordance with the "Reporting Guide for Laser Light Shows and Displays (21 CFR 1002)". If the basic show configuration changes then the new show should be described in a model change report;

LETI

99V-0556

3. a written notification to the CDRH 30 days prior to the show providing specific date(s), time(s), and location(s) with complete addresses for each assembly and presentation of the laser light show(s) and specific laser effects to be produced in each laser light show. If the venue of a particular show will require the show configuration to vary greatly from the configuration described in an initial or model change report, then plan and elevation diagrams for that particular show should be included in the notification. If the contract is not made thirty days prior to the show, it is permissible to phone in the notification to the CDRH and follow up the telephone conversation in writing referencing the date of the phone call and the person to whom the notification was made.

4. annual reports which summarize the contents of records maintained by the manufacture (see 1002.30(a)).

Initial, model change and light show reports are required to be filed prior to the introduction of a laser product into commerce. They are to include sufficient information to enable the determination of whether a manufacturer has correctly certified their products as being in compliance with the performance standard and conditions of the laser light show variance, if granted. Annual reports must be submitted by September 1, of each year and should describe the year beginning July 1, of the previous year and ending June 30, of that year.

Note that if laser light show display devices and displays having a continuous wave output in excess of 5mW are required to have an approved variance from the requirements of 21 CFR 1040.11(c) before introduction into commerce. Manufacturers of laser light show display devices, regardless of output are required to submit reports on their products as required by 21 CFR 1002.10 and 1002.12.

For aid in submitting the information required in the initial, model change, and laser light show reports consult the Compliance Guide for Laser Products and the appropriate reporting guide. Appendix B describes the requirements which are specific to laser light show display devices and displays. The use of the reporting guides is mandatory. The reporting guides can be obtained through the World Wide Web at the following website: WWW.FDA.GOV/CDRH.

You are reminded that production of laser light shows involving Class IIIb or IV levels of laser radiation without an approved variance in effect is in violation of Section 538 of the Act and subject to penalties of up to $1000 for each violation with a maximum penalty of $300,000.

Please submit the requested reports within 30 days of the date of this letter so that we may resume processing of your variance. Your reports should be submitted to: Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. If you have any questions regarding these requirements, please call (301) 594-4654.

Sincerely yours,

Susan Jensen

Susan Jensen
Consumer Safety Officer
Electronic Products Branch
Division of Enforcement III
Office of Compliance
Center for Devices and
Radiological Health